REMARKS

Claims 4, 9-32, 34-37, and 39-41 were previously pending in this application. By this amendment, claim 4 has been amended. New claim 42 has been added. As a result, claims 4, 9-32, 34-37, and 39-42 are pending for examination with claim 4 being an independent claim. No new matter has been added. Applicant's representative appreciates the Examiner's willingness to conduct the telephonic interview on October,10, 2003, the contents of which is summarized below.

As discussed in the October 10, 2003 telephonic interview, Applicant has added new claim 42 that depends from claim 4, which indicates that the sample of claim 4 is a saliva sample. Support for use of saliva as a sample in the methods of the invention can be found in the specification at page 12, lines 26-27. In addition, as discussed with the Examiner in the telephonic interview, Applicant files herewith a signed Declaration of the inventor, Dr. José Halperin, which provides descriptions and results of experiments done using the methods of the invention to detect levels of glycated and nonglycated CD59 in saliva samples. Applicant submits that the Declaration provides evidence that the methods of the invention are enabled for tissues and fluids such as saliva, in addition to being enabled for blood and urine samples. No new matter has been added.

Applicants respectfully request consideration of the newly added claim 42.

Rejections Under 35 U.S.C. §112, First Paragraph

The Examiner rejects claims 4 and 9-41 as lacking enablement commensurate with the scope of the claims.

Applicant has amended claim 4 to clarify the claim as discussed in the telephonic interview between Examiner VanderVegt and Applicant's representative, MaryDilys Anderson on October 10, 2003. As suggested by the Examiner in the telephonic interview, Applicant has amended claim 4 to clarify that the antibodies specifically bind K41-glycated CD59 or K41-non-glycated CD59. Applicant submits that an antibody specific for either K41-glycated or K41 non-glycated CD59 can be used to determine the level of glycated CD59 in a sample and have amended claim 4 to indicate this feature. Support for the amendment can be found at least at page 9, lines 18-20.

In the October 10, 2003 telephonic interview, Applicant indicated to the Examiner that the level of glycated CD59 can be determined directly using an antibody that is specific for K41-glycated CD59, and that the level of glycated CD59 can also be determined indirectly using an antibody that is specific for K41-non-glycated CD59 to assess the relative amount of K41 glycated CD59 to K41 non-glycated CD59. The level of K41 non-glycated CD59 can be determined in relation to the level total CD59, providing an indirect measurement of the level of K41 glycated CD59 in the sample. Applicant has amended claim 4 to indicate that the antibody is specific for K41-glycated CD59 or K41 non-glycated CD59. Support for the amendment can be found at least at page 13, lines 10-20 and page 14, lines 11-17 of the specification as filed.

In the telephone interview on October 10, the Examiner requested that claim 4 be amended to include a description of the relationship between the level of glycation of CD59 in a sample, the level of glycation of CD59 in a control, and the determination of onset, progression and/or regression of a condition. Applicants have amended the claim to include the description.

Applicant respectfully requests reconsideration and withdrawal of claims 4, 9-32, 34-37, and 39-41 under 35 U.S.C. §112, first paragraph in view of the amendments made above.

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment that the application is not in condition for allowance, the Examiner is requested to contact the Applicant's representative at the telephone number listed below.

Respectfully submitted,

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